IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| UNITED STATES OF AMERICA | : | CRIMINAL ACTION |
| | : | |
| v. | : | |
| | : | No. 09-403-4 |
| THOMAS B. HIGGINS | : | |

MEMORANDUM

Legrome D. Davis, J. December 7, 2011

On November 28, 2011, pursuant to 18 U.S.C. § 3143(b)(1),[1] Defendant Thomas B. Higgins moved for release pending appeal of his nine-month sentence of imprisonment for violations of the Federal Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399d; see 21 U.S.C. §§ 351(f)(1)(B), 352(f) and (o), 331(a), 333(a)(1). Seven days earlier when we imposed sentence, we initially remanded Higgins to custody. We subsequently granted Higgins' oral motion for a stay, delaying surrender until December 5 in order to allow him to arrange necessary medical care for his wife. On December 2, we further postponed Higgins' surrender until December 19 so that we might submit a formal document resolving the outstanding Motion for

[1] The statute, 18 U.S.C. § 3143(b)(1)(A), (B)(iii), and (B)(iv), provides in pertinent part:

> [A] person who has been found guilty of an offense and sentenced to a term of imprisonment, and who has filed an appeal . . . , [shall] be detained, unless the judicial officer finds –
>
> (A) by clear and convincing evidence that the person is not likely to flee or pose a danger to the safety of any other person or the community if released . . . ; and
>
> (B) that the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in – . . .
>
> (iii) a sentence that does not include a term of imprisonment, or
>
> (iv) a reduced sentence of imprisonment less than the total of the time already served plus the expected duration of the appeal process. . . .

Release Pending Appeal. (Doc. No. 182) Two hours later, Higgins withdrew his Motion from the docket in this Court. (Doc. No. 194) As the factual events in this matter are out of the ordinary, and a direct appeal is still pending, a fact-specific explanation of our sentencing decision is appropriate.

Medical devices are subject to the regulation and control of the Food and Drug Administration (FDA). The FDA's regulation centers on the degree of regulatory control necessary to ensure the safety and efficacy of a particular medical device. Class III significant risk devices are the most intensely regulated devices because the devices present a potential, unreasonable risk of illness or injury. See 21 U.S.C. §§ 351, 360c, 360e, 360j. The regulations are of substantial importance in preventing impairment of human health. Typically, since minimal safety information as to these devices exists prior to FDA approval, Class III devices gain approval only after successful completion of the FDA's most stringent review process – a lengthy undertaking that includes a careful examination of valid scientific test data. Only in this way can the FDA satisfy its duty to the public to ensure the safety and effectiveness of significant risk devices. Class III devices typically require premarket approval (PMA) or an investigational device exemption (IDE). The Synthes products at the heart of this case are Class III devices.

The 510(k) route is an alternate method for securing approval for medical devices, including Class III devices, where the manufacturer demonstrates that the new device is at least as safe and effective as a previously approved, or predicate, device. A 510(k) approval requires a showing of "substantial equivalence" to the predicate device. This means the new device will be used for the same purposes as the previously approved device, and the proposed device does not raise new questions of safety and effectiveness. This is a less intense, and much briefer, review

process.

Defendant Higgins served as President of Synthes' Spine Division from 1999 through January 2004 and Senior Vice President of Global Strategy, Synthes from February 2004 through May 2005. He pled guilty as a responsible corporate officer to the introduction into interstate commerce of adulterated and misbranded medical devices – in this case, two Class III significant risk medical devices, SRS mixed with barium sulphate and XR – in violation of 21 U.S.C. §§ 331(a) and 331(a)(1). Plea Agreement, ¶¶ 1, 9(A)-(J). These devices were adulterated because they were required to have, but did not have, in effect an approved application for premarket approval (PMA) or an approved investigational device exemption (IDE). Id. § 351(f)(1)(B). In part, the devices were misbranded because their labeling did not bear "adequate directions for use," id. § 352(f), and because the FDA was not provided with timely premarket notification of a new intended use prior to the introduction of the devices into interstate commerce for such use, id. § 352(o). The maximum statutory penalty for any person who violates a provision of § 331 is imprisonment for not more than one year. Id. § 333(a).

Although both devices were eventually cleared for use in the spine as general bone void fillers, neither device was ever cleared for use in load-bearing applications or for use in procedures to treat vertebral compression fractures, such as vertebroplasty[2] and kyphoplasty.[3]

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[2] Merriam Webster's Medical Dictionary defines "vertebroplasty" as "a medical procedure for reducing pain by a vertebral compression fracture (as that associated with osteoporosis) that involves injection of an acrylic cement (as methyl methacrylate) into the body of the fractured vertebra for stabilization – compare KYPHOPLASTY."

[3] Merriam Webster's Medical Dictionary defines "kyphoplasty" as "a medical procedure that is similar to vertebroplasty in the use of acrylic cement to stabilize and reduce pain associated with vertebral compression fracture but that additionally restores vertebral height and lessens spinal deformity by injecting the cement into a cavity created in the fractured bone by the insertion and inflation of a special balloon."

## FACTUAL FINDINGS

Without limiting in any way the voluminous record supporting these findings of Defendant's culpability, the following facts[4], which we find to be true beyond all reasonable question, and which serve as the foundation for our sentencing decision and determination that immediate incarceration is warranted, deserve special recognition. Importantly, this factual narrative focuses on the knowledge and behavior of Higgins himself, not his subordinates.

1. From the very beginning, Defendant Higgins planned a clinical trial of SRS without the FDA's approval. This was reflected in Higgins' February 24, 2000 e-mail to CEO Hansjörg Wyss, captioned "SRS for Spinal Applications – Action Plan Proposal." G Ex. 3. The plan amounted to a clinical trial before SRS was cleared for use as a general bone void filler in the spine through the 510(k) clearance obtained on December 20, 2001. The plan was to identify surgeons, select test sites, provide SRS product, train surgeons, observe surgeries, and compile and review data. All of this was to be done in 90 days.

2. Former Synthes Group Manager for the Regulatory and Clinical Spine Division Sands reported that, in 2000, Higgins asked Sands what the regulatory requirements would be to have Norian's bone cement approved for use in the spine, in vertebroplasty procedures. Sands stated that he told Higgins and others that an approved IDE was required before any study could be initiated. Sands further noted that there was "no way that these individuals could have misunderstood him." June 21, 2007 Report of Interview of Barry E. Sands ("Sands Interview") at 2, 5, submitted as Huggins Hr'g Ex. 6 at the evidentiary hearing held in this case on June 6-7, 2011. The precise date of Sands' conversation is uncertain.

3. Two of Dr. Delamarter's patients suffered hypotensive,[5] but nonfatal, events in February 2001 during surgeries/kyphoplasty procedures using CRS, a precursor Norian device that had the same chemical formulation as SRS. At that time, CRS was not cleared by the FDA for use in the spine. At some point in March 2001, Defendant Higgins learned of the two hypotensive events. Higgins knew that a Synthes sales representative had been present at the off-label surgeries. See March 15, 2001 e-mail from Michael

[4] These facts are principally derived from exhibits to the government's March 26, 2010 Presentence Memorandum, Doc. Nos. 93 and 94, which exhibits will be referred to as "G Ex. __ ."

[5] Merriam Webster's Medical Dictionary defines a "hypotensive" event as one that "caus[es] low blood pressure or a lowering of blood pressure."

Sharpe/Synthes to Dutcher/Synthes stating: "Both of these [events] were originally reported to Tom Higgins . . . ." G Ex. 37, Page 1DOJSYN.089.000339.

4. On March 19, 2001, Michael Sharp/Synthes Regulatory, sent an e-mail to Defendant Bohner and others at Synthes captioned, "Spine [T]est Market for SRS," G Ex. 19, stating in part:

> "Tom Higgins . . . requested that I meet with him . . . and I did so on September 5th [2000]. During that meeting I made it clear, or so I believed at the time, . . . we absolutely could not do anything which could be considered promotion of SRS for use in the spine. . . . I further told them that we could not do anything in our information gathering that might be construed as 'promoting or encouraging' off label use.
>
> Specifically, I told them that they could not ask surgeons if they had used SRS, how SRS had performed in this indication, possible problems or ways to improve the use of SRS for this procedure, how often they might use SRS for such a procedure, etc. I did concede that we could not stop a surgeon from using SRS, or any Synthes product for that matter, for an off-label indication but that we should not consider that fact a license to 'look the other way' and that if asked by a physician we should make it completely clear that the use was off-label and that we did not recommend it in any way. . . . Tom agreed.
>
> I also made it clear that the spine company should not be providing SRS to any account. No spine consultant should order SRS and spine PD [product development] should not provide . . . SRS to a surgeon. Since we have no spine indication for SRS my position was that there is absolutely no reasons that a spine consultant should ever be discussing SRS with a surgeon or providing the product. . . . Tom agreed with this position."

5. At a November 15, 2001 meeting, "Tom Higgins asked if we should consider a long-term IDE clinical study to follow-up patients with the vertebroplasty technique." Minutes at 2-3, G Ex. 5. A decision was made not to pursue an IDE clinical study for SRS mixed with barium sulphate, and instead, "to get a few sites to perform 60-80 procedures and help them publish their clinical results." Id. Higgins participated in this decision.

At the time this decision was made, Defendant knew that an IDE was required but it would be costly. An IDE would take about three years and a million dollars, and it was also clear that whatever competitive advantage Synthes continued to enjoy in the bone cement market would be lost. Transcript of Sentencing of Thomas B. Higgins ("Sentencing Tr.") 56:20-57:18, Nov. 21, 2011; see also Sands Interview at 2, Huggins Hr'g Ex. 6.

6. During a May 8, 2002 telephone conference with the FDA, Barry Sands, and other Synthes employees, the FDA noted the confusion that the current labeling procedures might cause over whether the bone fillers could be used in load-bearing areas. In particular, the "FDA expressed concern over the imprecision of the spine indication in the current indications for use of bone void fillers. . . . FDA asked that we provide additional labeling that specified load bearing indications, such as vertebroplasty, are not included in the current indication for use." Minutes, G Ex. 13. Sands stated that Synthes would "not promote this material (Norian XR) for such indications as vertebroplasty or other load bearing applications without the appropriate regulatory clearance." Sands Interview, Huggins Hr'g Ex. 6 at 3, 3-4. Barry Sands recalled that the FDA was insistent on language warning about use in load-bearing applications and vertebroplasty. Id. "Sands indicated that Synthes, including upper level management, clearly understood that Norian XR was not to be used for vertebral compression fracture procedures because the vertebral body '. . . is load bearing.' Sands stated there is no way it could [be claimed] he never made them aware of this." Id. at 4. Defendant Higgins received a copy of the minutes of the discussion with the FDA. G Exs. 35, 36 at 1DOJSYN.073.001959. The minutes were attached to Synthes' subsequent Special 510(k) submission for clearance of XR, which was granted December 19, 2002, with warning bullet "Not intended for treatment of vertebral compression fractures." G Exs. 43, 46.

7. In April 2002, the University of Washington began pilot studies on SRS commissioned by Synthes. One researcher, Dr. Jens Chapman, in a May 4-6, 2002 e-mail to Nisra Thongpreda/original Synthes Group Product Manager for SRS-R (which became XR), explained the alarming effect of SRS on a pig:

> "[T]he entire pulmonary artery system had clotted off. This could represent an uncontrolled activation of the coagulation cascade. . . . This clearly underscores the need for further investigation of the device while it is in the 'medication phase' . . . .
> [W]e were expecting to kill the pig . . . but not suddenly and with a relatively small dose. We also need to worry about a coagulogenic effect of the substance itself. . . ."

Higgins received this e-mail. Government Ex. 3, submitted at the June 6-7, 2011 evidentiary hearing in this case. Thus, Higgins knew no later than early May 2002 that the chemical composition of SRS – the specific formula of the calcium phosphate cement – itself posed lethal risks when used in the spine in vertebroplasties. He knew the cement was potentially dangerous in that it appeared to have a rapid and extreme coagulogenic effect in the blood of animals. He knew, or should have known, that the planned development of a cement to treat vertebral compression fractures was potentially suspect, and caution and strict adherence to regulatory procedure was required. Importantly, Higgins knew, or should have known, of the need for further testing before

the product could be safely used on humans.

8. On May 30, 2002, Defendant Higgins received an e-mail from Defendant Huggins, who expressed his "second thoughts" about the unauthorized clinical trial of SRS in vertebroplasties. G. Ex. 8. Huggins stated:

> "There appears to be some shipments being made of Norian for Spine use which we need to discuss. We discussed the need to perform a real study to test Norian. We shouldn't be sending out product without proper protocols, surgeon sponsors, etc. As you know we have gone to great lengths in SUSA to train surgeons on Norian's use. It seems Spine is bypassing the needed blocking and tackling without thinking this all the way through.
>
> In addition, I had a long conversation with Dr. Lambert who is very concerned about the Spine plan. I am now having second thoughts. . . ."

9. In June 2002 e-mails to Defendants Higgins and other high-level executives, a Synthes medical consultant strenuously warned the recipients that unauthorized clinical trials of SRS with cavity creation instruments were being conducted. The consultant urged that the trials amounted to "human experimentation whose only defense seems to be that it will be a small study. If there are many spine surgeons who, in spite of knowledge of the foregoing are comfortable using SRS, then you should be uncomfortable with those surgeons." G Ex. 32.

10. Defendant Higgins received further clear warnings of the risks of mortality in using SRS in vertebroplasties. In particular, a June 28, 2002 University of Washington letter addressed to David Paul/Synthes and copied to Defendant Higgins stated:

> "[W]e believe that vertebroplasty presents a unique risk of Norian's entry into the venous system with subsequent transport to the lung and a consequent risk of **serious morbidity or mortality**." "The Clinical Safety of Norian SRS – Grant Proposal" at 9 (emphasis supplied).

11. Higgins attended a September 17, 2002 "Management Review Board Meeting." Agenda and minutes, G. Ex. 35. It is noted that the topic of vertebroplasty was discussed and "Hansjörg Wyss [Synthes CEO] inquired about the test market set up and how surgeons, who are interested in the product, were to be trained."

12. On January 13, 2003, a patient of Dr. Barton Sachs died during a vertebroplasty/kyphoplasty using SRS mixed with barium sulphate. G Exs. 49, 50, 51. No medical device report (MDR) was filed and no autopsy was done.

13. Defendant Higgins along with others attended a "Pig Lab" at the University of

Washington on April 17, 2003, which Hamilton summarized in an April 21, 2003 e-mail to her file. G Ex. 60. Hamilton stated in part:

> "A relatively small amount of XR was able to cause a rather large sized clot (as long as 4 inches). The researchers hypothesize that this is exacerbated by the coagulagenic cascade and the affinity of blood to clot in a calcium rich environment."

14. On February 10, 2003, Higgins approved and signed the Final Market Introduction Plan for XR. G Ex. 3, United States' Consolidated Response to Defendants' Objections to Presentence Reports. The plan predicted a $3,211,031.53 first-year after-tax profit on an initial investment of $92,804.80, meaning an after-tax profit of 35 times the cost of raw materials. On July 15, 2003, a few days before the July 18, 2003 safety meeting, a packet of materials was distributed to those expected to participate in discussions at the meeting. The packet included the "Release to Market Strategy." G. Ex. 37, 1DOJSYN.089.000396.

15. Higgins attended a July 18, 2003 Safety Meeting, at which he was fully informed about the topics and concerns discussed at this meeting and the risks involved in the XR "release to market strategy." Packet of materials distributed to all attendees, G Ex. 37; PowerPoint, G Ex. 38; Minutes of meeting attended by Huggins, Higgins, and Bohner, G. Ex. 39. The packet of materials distributed to all attendees, G Ex. 37, stated in part:

> "Norian SRS with Barium Sulphate – Back Table Mixing. This part of the test market began in September 2002. [The FDA had not granted approval for the mixing process at this time.] Two sites were selected to participate. . . . Rollout of XR with Rotary Mixer. This expanded test market to begin in August 2003 includes eight test sites selected by Product Development plus eight test sites selected by AVPs and Regional Managers. The PD [product development] sites were selected based on publication interest, affiliation with treating vertebral compression fractures . . . . The last phase of the test market will occur in September 2003 . . . These eight sites encompass the last of those chosen by AVPs [area vice presidents] and RMs [regional managers]. . . ."

Defendants explicitly evaluated whether to abandon the project, or pursue business interests over the safety of patients. PowerPoint, G Ex. 38 ("release to market strategy" re: "Norian XR Options," including "Cancel project – Too unsafe."). A decision was made to proceed with the XR test markets:

> "Recommendation – Proceed with current test market plan. Need to establish a larger case base (need 200-300+ cases prior to release) at multiple sites. . . . Test market will provide a degree of confidence in what we expect our

> complication rate to be . . . . This will help us **determine our associated level of risk and decide what level is too high**." (emphasis supplied)

PowerPoint, G Ex. 38 at 1DOJSYN.089.000087. These determinations, of course, can be made properly only in accordance with FDA regulatory protocol. A test market cannot lawfully be used to determine the safety and efficacy of a significant risk medical device.

16. Higgins also attended an August 14, 2003 Strategic Planning Meeting. Minutes of the meeting, G Ex. 55. Higgins participated in the decision to proceed with the unauthorized clinical trials of XR to experimentally test the "safety of the technique with Norian XR" on human beings. Id.

See also G Ex. 58, Josi Hamilton/Synthes Product Manager's Aug. 28, 2003 e-mail to another Synthes employee, which was copied to Defendants Higgins and Bohner:

> "Norian XR is officially released to Test Market. We shipped to 13 Spine sites Wednesday afternoon, and have 4 cases scheduled for Friday!! – I want to thank everyone for their continued support with this project. Over the past 2+ years we've encountered multiple hurdles . . . The release of this product was truly a team effort and I couldn't have accomplished this without everyone's hard work & dedication."

See also G Ex. 59, J. Hamilton's Sept. 10, 2003 e-mail to Defendant Higgins regarding:

> "Norian XR Test Market – FYI – Dr. Ball had 2 more Cavity Creation XR cases today. He said they went 'perfect' . . . Dr. Garfin has a case tomorrow."

17. On September 19, 2003, a patient of Dr. Paul Nottingham died during a spinal surgery using XR. G Exs. 62, 66. No autopsy was done. A medical device report (MDR) was filed, but the report did not mention that the procedure was a vertebroplasty/kyphoplasty using XR.

18. Defendant Higgins attended and participated in the September 19-20, 2003 "Norian XR Test Market Kick-Off" session held in Charlotte, NC to train surgeons to use XR in vertebroplasties to treat vertebral compression fractures. G. Exs. 63, 64. Synthes' promotion of off-label use of XR directly to physicians is prohibited by FDA regulations.

19. Following the death of Dr. Nottingham's patient on September 19, 2003, Defendant Higgins attended a meeting held on September 23, 2003. G Exs. 62, 65, 66. In a September 23, 2003 memorandum, G Exs. 62 and 66, J. Hamilton summarized her interviews of two of the 19 surgeons selected for the XR clinical trials, stating in part:

> "During cement delivery . . . , a drastic drop in blood pressure was noted.

> . . . He [Dr. Nottingham] noted a cement leak during injection and feels this was the cause of the incident. He thinks our system is guesswork as to how much material to inject. He thinks a clinical trial is necessary before releasing . . . XR. He said he thought we had much greater clinical experience. He claimed the sales consultant 'pushed' this product on him and was unclear as to its status on the market."

J. Hamilton also interviewed Dr. Lane on September 23, 2003. On October 1, 2003, she sent an e-mail to Defendant Higgins about her meeting with Dr. Lane. G Ex. 68. Later that day, Hamilton's e-mail was forwarded to Defendants Bohner and Walsh. Hamilton stated in part:

> "Lane thinks Norian XR is potentially de-watering and causing episodes of hypotension . . . With our system he says there is no egress hole so the pressure can be too high . . . with an old fracture, the cement might not have a place to go, so a venous leak can happen . . . He believes Norian XR should have gone to the IRBs [Institutional Review Boards] of every participating hospital b/c [because] of the information we're collecting. . . . Lane thinks we should go to the FDA ASAP to understand what is necessary in order to change our labeling (Remove 'Not for use in Vertebral Compression Fractures')."

In J. Hamilton's October 15, 2003 e-mail to Defendants Higgins and other executives, G. Ex. 65, she informed the recipients of her interviews with all 19 of the surgeons selected to use of XR in vertebroplastic surgeries to treat vertebral compression fractures and the complications associated with this use of XR on the elderly patient population.

20. On October 31, 2003, Higgins attended a meeting convened in the aftermath of Dr. Nottingham's patient to consider serious questions that had arisen about the use of XR in unauthorized clinical trials. Meeting notes, G Ex. 67. Despite the second death and with knowledge of the risks, meeting participants decided to continue the experimental use of XR on humans.

21. Synthes Product Manager Josi Hamilton, in a November 19, 2003 e-mail addressed to Defendant Higgins, provided an "up-date" on the University of Washington's on-going XR studies. G Ex. 61. She stated in part:

> "There is not enough information yet for the surgeons to draw any conclusions regarding the clinical use of XR."

22. On January 22, 2004, a patient of Dr. Hieu Ball died during a kyphoplasty to treat a vertebral compression fracture. An autopsy was done and a medical device report (MDR) was filed, but the report did not mention that the procedure was a

vertebroplasty/kyphoplasty using XR. G. Exs. 74, 75.

23. The FDA investigated Synthes from May 11 through June 18, 2004. On November 5, 2004, the FDA issued a warning letter to Synthes, stating in part: "During the inspection . . . , the FDA learned that your firm is marketing the Norian XR for new intended uses without approval or clearance from the FDA, in violation of the Act. We also found violations of the Medical Device Reporting regulation . . . . 1DOJSYN.021.003329-003337; G. Ex. 79, FDA Establishment Inspection Report.

24. After the FDA's on-site investigation, Higgins and others drafted Synthes' response to the FDA warning letter. Collectively, Higgins and his fellow executives falsely stated that no clinical trials had occurred, that the test market had been conducted only for cleared indications, that the test market was not conducted for the purpose of testing the safety and efficacy of the bone cements, and that Synthes had not trained the surgeons to use the cements. Sentencing Tr. 69:17-71:24.

## CLAIMS OF ERROR

In the Motion for Release Pending Appeal submitted to this Court, Higgins raised five claims of error. As we are not certain of the basis of Higgins' pending appeal, we will discuss the claims raised in the motion for release in turn.

### A. The Court appropriately considered and balanced all § 3553(a) factors.

Defendant submits that the sentence imposed "bears little relationship to 'the nature and circumstances of the offense and the history and characteristics of the defendant.' 18 U.S.C. § 3553(a)(1)," and suggests that punishment was based only on considerations of general deterrence. Def. Br., Doc. No. 182 at 4; Transcript of Sentencing of Thomas B. Higgins ("Sentencing Tr.") 77:23-78:6, Nov. 21, 2011. As an initial matter, this Court considered each and every § 3553 factor and each argument advanced for mitigation of sentence by Defendant. Higgins' reputation as a "good and decent and moral man," who has lived a good life, was fully credited. Sentencing Tr. 11, 73. Defendant's individual history, experience, education, professional achievements, impressive good works and charitable acts, and personal and family

circumstances were fully taken into account. Indeed, this Court accepted most of Higgins' characterizations of his background and character. Defendant was also credited for his guilty plea.

Defendant takes exception to the importance this Court assigned to the nature and circumstances of the offense, § 3553(a)(1), the need for the sentence to reflect the seriousness of the offense, § 3553(a)(2)(A), the importance of providing just punishment, § 3553(a)(2)(A), and the need to afford adequate deterrence, § 3553(a)(2)(B).[6] The relevant conduct previously chronicled was obviously a significant sentencing consideration. United States v. Fisher, 502 F.3d 293, 307 (3d Cir. 2007) ("conduct relevant to sentencing enhancements must be proven by a preponderance of the evidence, and the resulting sentence is reviewed for substantive reasonableness on appeal"). As our Court of Appeals has instructed, "sentencing judges are free to find facts by a preponderance of the evidence, provided that the sentence actually imposed is within the statutory range, and is reasonable." Id. at 305 (citing United States v. Grier, 475 U.S. 556, 568-71 (3d Cir. 2006)).

To summarize thousands of pages of documents reviewed before the imposition of sentence, Thomas Higgins, as President of the Spine Division, planned and participated in the unlawful clinical trials. He is fairly described as having been the "hands on manager of the unlawful clinical trials." Sentencing Tr. 55:8-12, 77:5-13. He was the actual leader of the Spine Division from whom his subordinate corporate-actors received direction. He received contemporaneous reports from his managers and lower level employees on the conduct and

[6] Defendant focuses only on the § 3553(a) factors explicitly discussed in the Motion. Our consideration of the 3553 factors at the sentencing hearing was broader than recognized by counsel.

results of the trials. He was in front, up close, and in person on product development and all important decisions involving the bone cements. He was fully aware that patients in the clinical trials were being subjected to untested and unapproved medical devices and were being placed at risk without their knowledge or consent. Indeed, when Defendant and persons under his control conducted training sessions, the surgeons were not advised of the deaths or adverse events, even though one of the deaths had occurred on the first day of the September 19-20, 2003 forum. Moreover, as he acknowledged to Barry Sands and Michael Sharp in 2000, Higgins fully understood that the 510(k) process was not an appropriate approval route for the devices at issue. Thus, all subsequent events occurred under against the backdrop of Higgins' acknowledged awareness that the Synthes test market was outside the boundaries of the law.

Nonetheless, together with his fellow Synthes executives, Higgins arranged for the delivery of SRS mixed with barium sulphate and XR to physicians who were then trained to use the devices in experimental surgeries on human beings. They arranged for the illegal training of physicians in the off-label, and unapproved, use of medical devices. Higgins and his fellow executives discussed, but chose to ignore, repeated warnings of the potentially serious risks associated with using the bone cements in vertebral compression fractures. They deliberately circumvented the premarket approval and IDE processes for the novel use of their bone cements (thereby avoiding required careful study, scientific testing and explicit approval by the FDA), and instead surreptitiously sought and obtained a 510(k) exception, intentionally deceiving the FDA by failing to disclose their intended, and previously agreed upon, purposes.

As events progressed, all warnings as to the significant potential risks in the use of Synthes bone cements to treat vertebral compression fractures, whether received from surgeons,

consultants, or medical researchers, were ignored by Higgins and his co-defendants. As evidence of the devices' potential lethal properties mounted, Defendant and his fellow Synthes executives continued on their path. Higgins and his fellow co-defendants were resolute in pursuit of the test market in disregard of the clear and adamant warnings from Synthes' own consultant physician that the clinical trials amounted to illegal and dangerous human experimentation. The assurances made to the FDA that the products would not be used in vertebral compression fracture surgeries were explicitly dishonored. Higgins participated in each and every one of these decisions. He is also one of the approving signatories on the February 10, 2003, Final Market Introduction Plan for XR. G Ex. 3, United States' Consolidated Response to Defendants' Objections to Presentence Reports. The plan predicted a $3,211,031.53 first-year after-tax profit on an initial investment of $92,804.80 – an amazing 35:1 ratio of after-tax profit to cost. Id. Ultimately, three unsuspecting persons died during the Synthes clinical trials.

Defendant does not dispute that by virtue of his position as an officer he bears a responsible share for the furtherance of the unauthorized clinical trials and illegal promotion of the devices. However, he strenuously maintains that even though he pled guilty as a responsible corporate officer, as set forth in the Plea Agreement, paragraph 9(A) through (J), he did not know at the time that his conduct was illegal and he did not intend to violate the law. Defendant concludes that based on the facts expressly set forth in paragraph 9 of the plea agreement, he cannot be imprisoned. Defendant is mistaken that his plea of guilty to a strict liability offense ensures a sentence of probation commensurate with less blameworthy conduct. Higgins' protests ring hollow.

Higgins's guilty plea does not cabin or circumscribe the Court's consideration of relevant facts at sentencing because "'a judge may appropriately conduct an inquiry broad in scope,

largely unlimited either as to the kind of information he may consider, or the source from which it may come.'" Fisher, 502 F.3d at 299 (quoting the "fundamental sentencing principle" that was reaffirmed in United States v. Grayson, 438 U.S. 41, 50 (1978)); accord Dawson v. Delaware, 503 U.S. 159, 164 (1992); USSG § 1B1.3; 18 U.S.C. § 3553(a). As our Court of Appeals has explained, the process due an accused at trial differs from the process due a convicted person at sentencing. Fisher, 502 F.3d at 298-99. In reaching a sentence of imprisonment, the Court properly considered Defendant's conduct relevant to the offense of conviction as well as information concerning the safety and efficacy of the devices. See USSG § 6A1.3(b) & Commentary, citing United States v. Watts, 519 U.S. 148, 157 (1997) for the proposition: "Any information may be considered so long as it has sufficient indicia of reliability to support its probable accuracy."

This Court well understands and respects historical sentencing practices for responsible corporate officials under the Park doctrine. See United States v. Park, 421 U.S. 658 (1975). We agree with the sentences previously imposed on the conduct before those courts. This case stands alone. Unlike Park, this matter does not involve holding an unaware corporate executive accountable for vermin in a warehouse. The sentencing considerations with Higgins are far more stark and compelling. We have not been able to locate a single case that involves such carefully constructed, meticulously implemented, and patently illegal, clinical trials. It is axiomatic that it is improper to use test markets to assess the safety of Class III devices. Nor can we find a reported case evincing such a pattern of deception with the FDA. And we cannot find a case where the decision-makers ignored such clear warnings of the potentially fatal nature of the product for such an extended period. We certainly cannot find a case where the corporate actors

disregarded two deaths, even failing to provide notice of the first as required by law. Finally, and most importantly, Higgins' case stands apart from other Park doctrine cases because the criminal conduct at issue is his own.

This conduct is without compare. A probationary sentence would not adequately address the wrongfulness of this conduct. The damage to Higgins' reputation, which he urges constitutes sufficient punishment, is an insufficient sanction for it does not recognize, much less address, the magnitude of this illegal conduct. This extended course of intentional and knowing wrongful behavior does not fall within the heartland of the 0-6 month recommended Sentencing Guidelines range for responsible corporate officials. Swift and substantial punishment is necessary to approach justice here. For these reasons, we granted an upward variance of three months.

B. Defendant Higgins' sentence was not enhanced due to his silence at sentencing.

Defendant submits that he was punished with imprisonment because he did not testify at sentencing. Def. Br., Doc. No. 182 at 3. Defendant grounds this assertion on comments addressed by the Court to Defendant's counsel that "you're the only one that I'm going to get to talk, and you're the only one that I can ask questions of - - ." Sentencing Tr. 33:18-20, 34:7-8, 37:23-24, 38:24. This assignment of error amounts to a frivolous and misleading portrayal of the record. It is clear that the Court sought to understand how an accomplished and decent man came to participate in this extended course of callous and illegal behavior. Defendant's written statement provided no insight and no true answers for he acknowledged the wrongfulness of his conduct only through the lens of hindsight. To this Court, resolution of the question as to the cause of the conduct speaks to the character of the offender and the nature and circumstances of

the offense, and is therefore highly relevant in determining an appropriate sentence. In this vein, we spoke with counsel:

> Mr. Higgins is a very intelligent man. . . ? How could he not understand . . . the wrongfulness of the conduct? See, that's what I'm having a problem with... because we have good people who lived good lives. . . . [T]his is so fundamentally wrong. It's a total failure to exercise moral or professional judgment, and it's not an accident. It's not an interpretation. It's an objective fact where people sat down and talked about it in meetings. . .
>
> And I just am trying to understand what the discussions were, what the thought processes were. . . . I can't understand how he can sit in a room [if] he's very concerned about the adverse events, and he's distraught, how he can sit in the room adverse event after adverse event after adverse event and still choose to continue.

Sentencing Tr. 42:15-43:8. The Court continued:

> [T]here are two concepts here. The one is the strict liability, responsible corporate official. . . . But then there's a second issue, which we discussed; mens rea, intent, relevant circumstances. . . . And on the relevant circumstances, relevant conduct issue, . . . I went through every single piece of paper. And I identified . . . what each defendant did and what information was in their hands and what choices were made.
>
> And there's no ambiguity in my mind about what each defendant did.
>
> And so, I'm not so much looking at it in terms of a corporate official being strictly liable for - - and I understand the statute - - for the misbranding that occurred, because first of all this case isn't about misbranding. It's about something far greater and more serious than that. . . . [I]t's about a deliberate choice to circumvent the regulatory authority for purposes, as best I can discern, financial motivation. . . .
>
> And it's a choice that is made, and it was a choice that continued . . . in spite of all of the information that was provided from multiple sources, from the researchers, from the doctors that it's time to stop and re-examine from the deaths, . . .from the cautions and concerns that existed with respect to this novel process, from the communications with the FDA. . .
>
> [T]he issue that is really of concern to me is why did he make these choices, because I really would like to understand, because if there's something that we can all understand from this process I think that we, as society and . . . we as a Court, we are enhanced by it. We need to understand.

Sentencing Tr. 45:14-48:16. In no way do these comments, when fairly placed in their full context, demonstrate an intent to enhance Higgins' sentence because he chose not to speak at sentencing. To the contrary, I sought only to gain an understanding so that I might be completely fair with Higgins. The record plainly demonstrates the fundamental incorrectness of Higgins' position.

C. The First Amendment challenge does not warrant release pending appeal.

Defendant submits that he was impermissibly sentenced for conduct that is protected by the First Amendment. Def. Br., Doc. No. 182 at 4-5. Specifically, Defendant maintains that under Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011), he cannot be punished for "the fact that off-label procedures were discussed with physicians in connection with that test market." Id. at 4. Defendant did not raise this issue at the sentencing hearing. Apparently, Defendant Higgins has adopted here for the first time Defendant Walsh's argument that the Court should reject any increase of his sentence based on his approval of the Norian XR Technique Guide and CD-ROM. Def. Walsh Sentencing Mem., Doc. No. 163 at 15-25. Defendant Walsh concedes those materials included depictions of the off-label use of XR to treat vertebral compressions fractures. Also depicted was the patient who died on January 13, 2003 during an off-label vertebroplasty using SRS mixed with barium sulphate. Defendant Walsh submitted that under Sorrell, his selection and approval of the materials are protected by the First Amendment and "it would be unlawful to enhance [his] sentence based on what is protected First Amendment expression." See Def. Sentencing Mem., Doc. No. 163 at 15-16, 17 n.3, 21-22.

The First Amendment challenge does not constitute a substantial ground for appeal.

Errors in sentencing that are not raised before the district court are subject to plain error review, "meaning that, in order to prevail on appeal, a defendant must establish an error that is plain, which affected his substantial rights, and which, if not rectified, would seriously affect the fairness, integrity or public reputation of judicial proceedings." United States v. Ward, 626 F.3d 179, 183 (3d Cir. 2010). In Higgins' case, none of the requisite elements for review are satisfied because there was no error. The Constitution does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent. Wisconsin v. Mitchell, 508 U.S. 476, 484, 489 (1993). There is no *per se* constitutional barrier erected to the admission of speech at sentencing simply because that speech is protected by the First Amendment. See Dawson, 503 U.S. at 164-65 (concluding evidence of one's beliefs and associations with others may be considered at sentencing where such evidence is relevant to the issues involved).

Defendant Higgins personally participated in the decisions to proceed with unauthorized clinical trials to test the safety and efficacy of SRS and XR on humans. As an integral part of that plan, Defendant Higgins participated in the physician training sessions. Defendant Walsh prepared and approved the Technique Guide and CD-ROM for use by Synthes' sales force in training physicians to use XR to treat vertebral compression fractures. Defendants' discussions with surgeons and the training materials were not purely educational in any abstract meritorious sense. They were tools used to advance the goals of the unauthorized clinical trials. It is not speech that is being penalized here. Even if it were, the First Amendment does not protect false and misleading speech. Defendants used the off-label cases in a manner to mislead the physicians into believing the products could be used safely. To say that the physicians were "sophisticated and experienced" does not mean that they were not misled by the inclusion of off-

label cases. The reading of the XR label word-for-word during the training sessions did not cure the lack of critical information about the product's dangers.

The First Amendment does not apply to the conduct for which Higgins is being penalized. Higgins personally participated in an elaborate, carefully implemented, scheme to deliver adulterated and misbranded medical devices to physicians for ultimate use on unknowing, and completely uninformed, medically frail patients. Higgins' conduct, not his speech, is the gravamen of this offense.

D. Imprisonment for a strict liability offense is appropriate here.

Defendant Higgins further submits that it was error to impose a term of imprisonment for a strict liability crime, "thus rendering the underlying conviction and sentence unconstitutional." Def. Br., Doc. No. 182 at 2. This assertion apparently challenges the constitutionality of the statute on its face, which provides for a maximum term of imprisonment of not more than one year. Defendant also contends his conviction as a responsible corporate officer for a strict liability offense is "constitutionally permissible only where the penalties are 'relatively small' and conviction does not cause 'grave damage to an offender's reputation.'" Id. (citing Morissette v. United States, 342 U.S. 246, 256 (1952). In Defendant's view, the imposed sentence of nine-months of imprisonment is not "relatively small."

Morissette decided "quite a different question" concerning the constitutional parameters of a conviction for conversion of government property without proof of intent. 342 U.S. at 248. Morissette did not decide the constitutional boundaries of strict liability crimes proscribed by statutes and regulations directed to health and welfare concerns. Id. at 248, 253-54. Defendant does not explain why Morissette should be applied to the circumstances presented here. Nor

does Higgins provide a reason to depart from the teachings of Park, which held that the FDCA "imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions." 421 U.S. at 676 (1975) (decided after Morissette). Under Park, a conviction based on strict liability for the offense in this case is permissible. Id. at 673 ("The Act does not . . . make criminal liability turn on 'awareness of some wrongdoing' . . . ."); United States v. Dotterweich, 320 U.S. 277, 280-81 (1943) (In the interest of the "larger good" of keeping impure and adulterated food and drugs out of the channels of commerce, the statute "dispenses with the conventional requirement for criminal conduct-awareness of some wrongdoing.").

Defendant has not presented any reason to question the constitutionality of Park as applied to the circumstances presented here. "The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them." Park, 421 U.S. at 672, 669-672. As the Supreme Court explained, "Congress has seen fit to enforce the accountability of responsible corporate agents dealing with products which may affect the health of consumers by penal sanctions cast in rigorous terms, and the obligation of the courts is to give them effect so long as they do not violate the Constitution." Id, at 673.

Defendant, who disclaims any knowledge of wrongdoing but pled guilty as a responsible corporate officer, was punished by imprisonment for a term within the statutorily prescribed maximum "for not more than one year." 21 U.S.C. § 333(a). Defendant cannot credibly claim

surprise or lack of notice as to a sentence of imprisonment.[7] Disappointed hopes for probation do not constitute a constitutional infirmity in the sentence imposed. Nor can he credibly contend that the sentence was substantively unreasonable. See discussion infra.

E. Defendant was not sentenced for a crime for which he was not convicted.

Defendant apparently contends that he was sentenced for a crime other than the crime of conviction in violation of the Due Process Clause of the Fifth Amendment. Def. Br., Doc. No. 182 at 2-3. This claim is not entirely clear but appears to be grounded on isolated and truncated comments by the Court and prosecutor at sentencing. See Def. Br., Doc. No. 182 at 3; Sentencing Tr. 46:8-12, 47:24-25, 63:19-22, 65:9-10. Higgins' argument ignores the fact that he was indicted, pled guilty, and sentenced for both misbranding significant risk devices and participating in an illegal clinical trial. In part, the devices were misbranded because their labeling did not bear "adequate directions for use," id. § 352(f), and because the FDA was not provided with timely premarket notification of a new intended use prior to the introduction of the devices into interstate commerce for such use, id. § 352(o). The devices were adulterated because they were required to have, but did not have in effect an approved application for premarket approval or an approved investigational device exemption (IDE) before they were delivered to the physicians. Higgins pled guilty to all of these violations. Plea Agreement, ¶¶

[7] See also Plea Agreement, ¶ 7(a), Doc. No. 42 (agreeing that at the time of sentencing, the government will "[m]ake whatever sentencing recommendation as to imprisonment . . . the government deems appropriate"), ¶ 8 ("The defendant understands, agrees and has had explained to him by counsel that the Court may impose the following statutory maximum sentence: . . . One year imprisonment . . . .").

(H) and (I).[8] This claim is without merit.

## CONCLUSION

Higgins betrayed the trust of his office and his position of leadership. Over the course of several years, he personally compromised and undermined the FDA's largely voluntary system for regulation of medical devices. He misled and manipulated surgeons by failing to provide accurate and complete information as to the significant risks associated with the use of Synthes bone cements in vertebral compression fracture surgeries. Sadly, he exploited and harmed vulnerable patients who necessarily relied on the integrity of professional judgments, which they had insufficient information to question. This extended course of conduct is without parallel in the universe of Park doctrine cases. Under the statutory framework, nine-months immediate

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[8] Defendant agreed that "if the case had gone to trial, the United States would have proven the following, which is the basis for the plea . . ." :

> (H) Between August 2002 and December 2003, Synthes and Norian trained spine surgeons to mix Norian SRS with barium sulphate and to use the resulting medical device in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian SRS stated that the product was not to be mixed with any other substance. This training of surgeons to mix Norian SRS with barium sulphate for the treatment of VCFs violated 21 U.S.C. §§ 351(f)(1)(B), 352(o) and 352(f)(1) because the mixing made SRS a new device that required premarket approval or clearance for this new intended use, and that lacked adequate directions for such use.
>
> (I) Between August 2003 and January 2004, Synthes and Norian trained spine surgeons to use Norian XR in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Noriam XR warned that the product was not intended for treatment of VCFs. This training took place as part of a so-called "test market" for Norian XR. As part of the XR "test market," Synthes and Norian directed the Synthes Spine sales force to gather clinical data about surgeries that the "test market" surgeons performed, so that Synthes and Norian could document the results of surgeries to treat VCFs, in order to assess the risk level of using Norian XR to treat VCFs, and determine whether that risk level was too high. This unauthorized clinical testing of Norian XR for the treatment of VCFs violated 21 U.S.C. § 351(f)(1) because such testing of a significant risk device required the prior approval of the FDA, through an IDE.

Plea Agreement, Doc. No. 42 at 4, 7, 8.

incarceration is the minimally appropriate sanction.

BY THE COURT:

/s/ Legrome D. Davis

Legrome D. Davis, J.